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## INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE

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PRACTICAL MECHANISMS FOR THE DEFENSIVE PROTECTION OF TRADITIONAL  
KNOWLEDGE AND GENETIC RESOURCES WITHIN THE PATENT SYSTEM

*Document prepared by the Secretariat*

### I. OVERVIEW

1. This document summarizes the products for the defensive protection of traditional knowledge and genetic resources which have been produced by the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ("the Committee"). It also reviews certain substantive issues that have arisen during the work of the Committee and identifies areas for future work by other WIPO bodies.

2. The term "defensive protection," when applied to traditional knowledge and genetic resources, refers to measures aimed at preventing the acquisition of intellectual property rights over traditional knowledge (TK) or genetic resources by parties other than the customary custodians of the knowledge or resources.<sup>1</sup> The development of measures for defensive protection have constituted a major component of the work of the Committee. An overview of the outcomes produced by the Committee is contained in Annex 1. The present document contextualizes these deliverables within their overall substantive context and a package of policy measures and practical tools for the concerned stakeholders.

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<sup>1</sup> See the overview of forms of legal protection provided in document WIPO/GRTKF/IC/5/12, from paragraph 17, and the discussion of defensive protection from paragraph 28.

3. In the work of the Committee, it has frequently been stressed that protection of TK should be undertaken in a comprehensive manner, potentially using both positive and defensive forms of protection. Defensive protection is no substitute for positive protection, and should not be mistaken for the acquisition and active exercise of rights in the protected material. Its impact is limited to preventing other parties from gaining intellectual property (IP) rights, and does not in itself prevent others from using this material. Often, the active assertion of rights (positive protection) is necessary to prevent the unauthorized or illegitimate use of TK. In some scenarios, defensive protection may actually undermine the interests of TK holders, particularly when this involves giving the public access to TK which is otherwise undisclosed, secret or inaccessible. In the absence of positive rights, public disclosure of TK may actually facilitate the unauthorized use of TK which the community wishes to protect.

4. This document provides an overview of defensive protection measures in the following structure: Section II sets the work of the Committee in context with a case study and some background information regarding defensive protection of genetic resources and TK. Section III sets out considerations for effective defensive publication strategies. Sections IV and V review the outcomes which the Committee has delivered through these Activities in four sessions. These outcomes include both amendments to existing international patent systems and practical tools for stakeholders. Section VI identifies some areas for future work. Finally, Section VII presents some preliminary conclusions. Annex I sets out a summary table of all the Deliverables and Products produced by the Committee for Defensive Protection of TK and genetic resources. Finally, Annex II provides some background information on the System-wide Information Network on Genetic Resources (SINGER) of the Consultative Group on International Agricultural Research (CGIAR), a global database of genetic resources which has been linked to the WIPO Portal of Online Databases and Registries Concerning TK and Genetic Resources.

## II. DEFENSIVE PROTECTION : BACKGROUND

5. Defensive protection in the context of the patent system hinges on the requirement that inventions be both novel (new) and inventive (non-obvious). Both of these criteria are assessed with reference to available prior art: that is, information which was available to the public before the filing or priority date of the patent application. This has a legal aspect and a practical aspect. Legally, the criteria concern all information that is available to the public prior to the filing date or priority date of the patent application. National laws specify what information should be taken into account. For example, at the international level, the Patent Cooperation Treaty (PCT) Regulations (Rule 33(1)) provide that:

“relevant prior art shall consist of everything which has been made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations) and which is capable of being of assistance in determining that the claimed invention is or is not new and that it does or does not involve an inventive step (i.e., that it is or is not obvious), provided that the making available to the public occurred prior to the international filing date.”

However, this rule only directly concerns the non-binding international search and examination, and the applicable rules for determining what prior art is relevant can vary

according to national or regional laws. A strategy for defensive protection clearly needs to take account of the legal situation that applies in any particular country of interest.

6. Practically, during the examination of a patent application, it is not possible to locate literally all potentially relevant information. Even so, it is clearly desirable for examiners to have access to any relevant information, so that when a decision is taken on granting a patent, it is based on as full a background of prior art as is possible. Defensive strategies may therefore involve increasing the practical likelihood that an examiner will locate and consider the relevant information. For example, an obscure publication that is only available in a library in a foreign country will not normally be available to (or even known to) a patent examiner, even though it would be considered relevant prior art if the examiner or other authority had access to it or was aware of it. In practice, an obscure document or publication may not be known to the patent or judicial authorities. A defensive strategy might involve republishing that publication in a form accessible on the internet, linking it to particular search tools, or including it in a database of materials specifically identified as relevant for patent examination in a particular field.

7. Defensive strategies therefore have two aspects:

- a legal aspect, ensuring that information is published or documented in such a way as to meet the legal criteria to be counted as prior art in the jurisdiction concerned (this may include, for instance, ensuring that there is a clear date of publication, and that the disclosure enables the reader to put the technology into effect); and
- a practical aspect, ensuring that in fact the information is available to search authorities and patent examiners, and is readily accessible (such as through being indexed or classified), so that it is likely to be found in a search for relevant prior art.

#### *Monitoring patent activity*

8. Implementation of defensive strategies may also include an element of actively monitoring patent applications and patent grants, including the possibility of taking legal action in relation to patents which may have negative consequences – for instance, in restraining freedom to operate in the use of technologies. For instance, a defensive strategy might include monitoring newly approved patents in a particular country, with a view to lodging opposition to any applications of concern and avoiding the grant of patents that might create difficulties. This may involve monitoring patent activity by particular companies or certain inventors, monitoring specific areas of technology (for instance, according to the International Patent Classification (IPC)), or tracking the progress of a specific application. Commercial services are available for monitoring patents, and the increasing Internet access available to national patent records has greatly increased the capacity of individuals to obtain information on patent activities. Due to the transparency of the patents system, monitoring patent activity has also been used as a means of tracking research and commercial activity generally. In the area of TK and genetic resources, for instance, the relative ease of monitoring patent activity has provided opportunities to scrutinize not merely patent applications concerning TK and genetic resources, but also research and commercial activities making use of TK and genetic resources, to the extent that these are made public through the disclosure function of the patents system. Existing patents systems have therefore yielded considerable information about the relationship between the patents system, and genetic resources and associated TK. There are also a number of proposals in international fora for

specific disclosure mechanisms that would concern TKO genetic resources used in developing an invention that is the subject of a patent application: these are also present in several national or regional patent systems. A number of Committee participants have raised these mechanisms as a part of an approach to defensive protection (see for example WIPO/GRTKF/IC/4/15, paragraphs 103 and 133). Such mechanisms are discussed at length in document WIPO/GRTKF/IC/5/10.

### *Defensive publication strategies*

9. Defensive protection of innovations is an important component of the IP strategies of many creators and innovators. For example, R&D corporations may publish inventions or other technologies which they have elected not to protect by seeking patent rights. In this way, they preserve the right to use the invention against any third parties whom they may later seek to patent similar or derivative inventions. The information that has already been published may count as prior art in assessing whether a later patent application is novel or inventive. In turn, this makes it less likely that a patent will be granted that would interfere with the use of the technology the company wishes to use. Some defensive publications are printed in-house by the companies and distributed to libraries and patent offices. The *Xerox Disclosure Journal*<sup>2</sup> and International Business Machine's *IBM Technical Disclosure Bulletin*<sup>3</sup> are two well-known examples of publications issued by companies in order to disclose their innovations as part of a defensive protection strategy. Other examples include the *Bell Laboratory Record* and the *Siemens Zeitschrift*.

10. Organizations or companies that do not publish their defensive publications themselves often rely on established defensive publication services. These services publish details of inventions in paper form in their journal and in digital form in their online electronic databases, and distribute these to patent offices. For example, *Research Disclosure*, which was initiated in the 1950s and forms part of the PCT Minimum Documentation, is published monthly as a paper journal and as an online database product.<sup>4</sup> More recently, IP service companies, such as IP.com, offer integrated security services ranging from safeguarding sensitive information (such as R&D Lab Notebooks) to other rapid publication of technical disclosures.<sup>5</sup>

<sup>2</sup> See < <http://www2.xerox.com/research/xdj/>>. The Xerox Disclosure Journal (XDJ) is published bi-monthly and is in its twenty-fifth year of publication. The last issue of each year contains an index both by U.S. Patent Classification and by author name placed at the end to complete the volume set.

<sup>3</sup> The IBM Technical Disclosure Bulletin issues up to September 1997 are now viewable online from Delphion's Intellectual Property Network Website. See <<http://www.ibm.com/ibm/licensing/patents/disclosures.shtml>>.

<sup>4</sup> See <[www.researchdisclosure.com](http://www.researchdisclosure.com)>. Research Disclosure (RD) is an international defensive publication service that allows inventors, scientists and companies to quickly establish prior art, in any language they choose. It is published monthly as a paper journal and as an online database product with advanced full text searching capabilities. RD's archive of searchable disclosures are available for online searching. RD also allows disclosures to be published anonymously. The disclosure text is under the control of the disclosing party. RD has been repeatedly and successfully cited in challenges to patents granted after prior art disclosure.

<sup>5</sup> See <[www.ip.com](http://www.ip.com)>. IP.com maintains a Prior Art Database and the *IP.com Journal*, both of which served defensive publication purposes.

11. Patent offices may also provide for forms of defensive publication, such as the system of Statutory Invention Registration under the law of the United States of America (35 USC 157), which is accessible and searchable alongside other patent literature. It is possible to file regular patent applications for defensive purposes, rather than with the aim of securing positive rights in the invention as such. This was described in documents WIPO/GRTKF/IC/5/7 and WIPO/GRTKF/IC/5/8 as 'the practice of applying for patents for inventions that the applicant does not intend to use, but which he or she does not want to fall in the hands of competitors whom may independently reinvent them. A practical also option is to file a patent application, to wait for it to be published (or "laid open for public inspection") and not to request the subsequent examination. It may be noted that many countries publish patent applications after 18 months. Such application thereby falls into public domain and as such it will necessarily be taken into account by patent examiners when assessing the patentability of claims filed by competitors.' In practice, many countries publish patent applications after 18 months. It is also possible, in many patent systems, to request the early publication of a patent application, for instance as a defensive strategy.

12. While defensive protection is a relevant IP strategy in all fields of technology, there has been particular recent interest in defensive publication concerning inventions based on genetic resources and on TK.<sup>6</sup> This has led to discussion about what steps, legal or practical, may be necessary to improve the possibility of patent -granting authorities identifying relevant prior art during the examination of the patent application. This prior art may be traditional knowledge, or it may be information about genetic resources.

13. There is, arguably, a shared interest among patent applicants, patent -granting authorities, and the general public in ensuring that patents are granted on the basis of as full as possible an awareness of existing prior art. From the point of view of the patent applicant, this means that the patent, once granted, is less likely to be reversed if challenged in court, as it is less likely that adverse prior art will later be located and cited against the patent. From the point of view of the patent -granting authorities and the general public, this means that the scope of patent rights, once granted, conforms more closely to the public interest as defined in patentability criteria.

#### *Defensive protection of genetic resources: an illustrative example*

14. The practical operation of defensive protection may be illustrated by a case that was recently considered by the Commission on Genetic Resources for Food and Agriculture (CGRFA) of the FAO, pursuant to a submission from the International Center for Tropical Agriculture (CIAT).<sup>7</sup>

<sup>6</sup> See, for instance, "Defensive Publication" in Chapter 4 of "People, Plants, and Patents: The Impact of Intellectual Property on Trade, Plant Biodiversity, and Rural Society," The Crucible Group, 1994

<sup>7</sup> The International Center for Tropical Agriculture (CIAT) is a non-profit, nongovernmental research organization dedicated to alleviating hunger and conserving natural resources in developing countries. It is one of sixteen international agricultural research centers which form part of the Consultative Group on International Agricultural Research (CGIAR). See: <<http://www.ciat.cgiar.org/>>

*Background: International Agricultural Research Centres*

15. The International Agricultural Research Centres of the Consultative Group on International Agricultural Research (CGIAR) hold the world's most important *ex situ* collections of the germplasm of major food crops. In 1994, twelve CGIAR centres, CIAT included, concluded agreements with FAO in 1994,<sup>8</sup> bringing their collections into the International Network of *Ex Situ* Collections under the Auspices of FAO, and recognising the "intergovernmental authority of FAO and its [CGRFA] in setting policies for the International Network." They agreed to hold the designated germplasm "in trust for the benefit of the international community", and "not to claim ownership, or seek intellectual property rights, over the designated germplasm and related information," and to lay this obligation on any subsequent recipients of material from their collections. This was recognized to be an interim solution, pending the completion of the negotiations for the International Treaty on Plant Genetic Resources for Food and Agriculture. The Treaty<sup>9</sup>, adopted on 3 November 2001, in Article 15, recognizes "the importance to this Treaty of the *ex situ* collections of plant genetic resources for food and agriculture held in trust by the IARCs of the CGIAR." It makes provisions for the IARCs of the CGIAR and other International Institutions holding *ex situ* collections of plant genetic resources for food and agriculture, bringing them under the terms of the Treaty.

*Example of a field bean cultivar*

16. The present case is cited merely to illustrate the practical question that may arise in relation to patent examination and grant in relation to inventions making use of genetic resources. The question of whether an individual patent is valid or not is entirely a question of national law (or regional law where applicable), to be determined by the appropriate national or regional authorities. This case concerns United States patent 5,894,079, issued on April 13, 1999, entitled "Field bean cultivar named denola." This patent was granted for a new cultivar of field bean (*Phaseolus vulgaris* L.) which produces a distinctly yellow seed with a yellow hilum that remains relatively unchanged over time. The invention also relates to a method of producing a field bean cultivar by crossing a first parent field bean plant with a second parent field bean plant, wherein the first or second field bean plant is that of the invention.<sup>10</sup>

17. According to CGRFA documents<sup>11</sup>, questions were raised about the validity of this patent, which "restricts the use of designated bean germplasm with yellow seeds for purposes of agronomy and breeding in the USA, even though the FAO-CGIAR Agreement expressly prohibits the claiming of intellectual property rights on designated germplasm, even for accessions distributed before their designation [...]. In addition, the patent does not fulfill

<sup>8</sup> Available at < <ftp://ext-ftp.fao.org/ag/cgrfa/GS/cgtexte.pdf> >.

<sup>9</sup> The text of the Treaty was made available to the Second Session of the Inter-governmental Committee as document WIPO/GRTKF/IC/2/INF.2, and is at <[http://www.wipo.int/eng/meetings/2001/igc/doc/grtkfic2\\_inf2.doc](http://www.wipo.int/eng/meetings/2001/igc/doc/grtkfic2_inf2.doc)> Seed document CGRFA -9/02/Inf.7, page 1.

<sup>11</sup> Document CGRFA -9/02/11, Report on the International network of *Ex Situ* Collections under the Auspices of FAO, paragraphs 23- 26 <<ftp://ext-ftp.fao.org/ag/cgrfa/cgrfa9/r9w13e.pdf>> and document CGRFA-9/02/Inf.7, Report on the International Network of *Ex Situ* Collections under the Auspices of FAO: further information provided by the International Centre for Tropical Agriculture (CIAT), regarding its request for a re-examination of U.S. patent No. 5,894,079 <<ftp://ext-ftp.fao.org/ag/cgrfa/cgrfa9/r9i7e.pdf>>.

two basic requisites: newness, and non-obviousness.”<sup>12</sup> The question of the terms of access to CGIAR collections are not dealt with at all in this example, and indeed, as noted below, it has been pointed out by some FAO Member States that “the material had not in fact come from the trust collections.” This example addresses only the novelty and non-obviousness requirements, which ultimately are specific legal questions considered by national authorities who apply national patent law on the basis of the patent claims considered in the light of any relevant prior art that has been identified. However, there is also the practical question of how to locate and identify relevant prior art and to make this information available in a form that can be used for patent procedures. Various legal processes are available under national or regional patent laws for the validity of a patent to be reviewed, including in the light of prior art newly brought to the attention of patent or judicial authorities. Re-examination by the United States Patent and Trademark Office (USPTO) is one such national procedure.

18. In 2000 the Director General of CIAT indicated that “the ‘Enola’ bean is close to several yellow-seeded bean varieties deposited in the trust collection held at the Centre,” and that CIAT “will continue to distribute freely such germplasm accessions in the framework of the FAO-CGIAR Agreement.”<sup>13</sup> CIAT-BRU used microsatellites (a form of molecular marker) to survey 21 bean lines from the CIAT collections with yellow seeds and hilum. “Enola” was discovered to be genetically very close to the CIAT accessions G22227 and G14024. G22227 is a breeding line from northwestern Mexico and G14024, also known as “Peruano”, is a bean line that CIAT obtained from Mexico, but which is originally from Peru. CIAT-GRU also showed that “Enola” has “T” phaseolin, a marker that is common among wild forms and landraces of the Central Andes of Peru.<sup>14</sup>

19. In March 2000 the Director General of CIAT issued a letter indicating that the “Enola” bean is substantially identical in all important respects to a number of accessions held by CIAT in its genebank. In May 2000, the FAO Legal Office sent a letter to the Director General of CIAT supporting the latter’s intention to bring the matter to the attention of the USPTO. On December 20, 2000, CIAT requested re-examination of the patent. The reasons for the request for re-examination were:

- (a) that the use of bean designated germplasm with seed of yellow color might be restricted by the patent for agronomy and other breeding purposes in the USA, and
- (b) that two basic requisites for granting the patent (namely novelty and non-obviousness) were not fulfilled.

On February 8, 2001, the USPTO indicated that it would re-examine the patent.

20. At the ninth session of the CGRFA, held from October 14 to 18, 2002, CIAT provided updated information on CIAT’s request for re-examination of the patent.<sup>15</sup> Additionally, this specific patent case and the question of “intellectual property rights... being sought by third parties over designated germplasm provided by the CGIAR Centres” were brought to the CGRFA’s attention in the “Report on the International Network of *Ex Situ* Collections under

<sup>12</sup> CGRFA-9/02/Inf.7, page 2.

<sup>13</sup> Seed document CGRFA-9/02/Inf.7, page 2.

<sup>14</sup> Seed document CGRFA-9/02/Inf.7, page 3.

<sup>15</sup> Seed document CGRFA-9/02/Inf.7.

the Auspices of the FAO.”<sup>16</sup> The deliberations of the Commission are summarized in the Report of the ninth session as follows:

“A number of countries expressed concern over cases involving the inappropriate granting of intellectual property rights over materials from the International Network, noting, however, that such cases had all been attended to. The Commission was informed of ongoing litigation by the International Centre for Tropical Agriculture (CIAT)... Some members of the Commission expressed concern that inappropriate granting of intellectual property rights could jeopardize public confidence in the in-trust collections held by the Centres within the International Network, and requested the Director General of FAO to bring the matter to the attention of the United Nations General Assembly and the World Trade Organization, and to forward the documents, *Report on the International Network of Ex Situ Collections under the Auspices of the FAO*, and *Report on the International Network of Ex Situ Collections under the Auspices of the FAO: Further Information Provided by the International Centre for Tropical Agriculture (CIAT), Regarding its Request for Re-examination of U.S. Patent No. 5,894,079*, to the World Intellectual Property Organization (WIPO) and its various Committees, with a request that WIPO cooperate with FAO in preparing a study on how intellectual property rights may affect the availability and use of material from the International Network and the International Treaty. Other Members noted that the material had not in fact come from the in-trust collections, and that the FAO had already supported CIAT’s claim against the Patent.”<sup>17</sup>

21. Such discussions in genetic resource policy for an individual patent case may raise broader policy or legal issues, which are not touched on in the present document. However, this case also illustrates the practical context of defensive protection strategies in the field of genetic resources. Put simply, the question is one of how to increase the likelihood that relevant information about genetic resources is available to patent-granting authorities, that this information is available at an early stage in patent processing, and that this information will in fact be located and assessed during the initial examination of the patent application. The development of extensive information tools and data collections in the field of genetic resources makes this an increasing practical possibility. This information becomes especially important when it relates to public domain or open access international collections of germplasm. It also brings into focus the substantial procedural costs which a national public or international institution may have to shoulder in challenging a patent, an important matter to take into account in considering defensive protection strategies, particularly when there is no possible financial benefit for the institution if its challenge succeeds.

#### *Information on genetic resources*

22. Information regarding most accessions in ex-situ collections held by International Agricultural Research Centers of the CGIAR, such as CIAT, is publicly available on the internet in the System-wide Information Network on Genetic Resources (SINGER) of the Consultative Group on International Agricultural Research (CGIAR).<sup>18</sup> SINGER is

<sup>16</sup> Seed document CGRFA -9/02/11, paragraphs 23 to 26.

<sup>17</sup> Seed document CGRFA -9/02/REP Report of the Commission on Genetic Resources for Food and Agriculture, paragraphs 31 available at: < <ftp://ext-ftp.fao.org/ag/cgrfa9/r9repe.pdf>>.

<sup>18</sup> The SINGER is available at < <http://www.singer.cgiar.org/>>.



maintained by the System-wide Genetic Resources Programme (SGRP) of the CGIAR, which is hosted by the International Plant Genetic Resources Institute (IPGRI). The SINGER provides access to information on the collections of genetic resources held by the CGIAR Centres, most of which are held in trust under the auspices of the FAO. In total, SINGER contains information on over 600,000 samples of crop, forage and tree germplasm of major importance for food and agriculture. (Not all collections held by the Centres are included in SINGER.) SINGER links the genetic resources databases of the CGIAR Centres and allows simultaneous searches for information concerning the identity, source, characteristics and transfer of the genetic resources in the individual Centre collections. It is important to note that the SINGER Database does not include exhaustive information about the accessions held. Further information about accessions can be obtained from the Centres holding them. The exclusive use of the SINGER Database could not constitute due diligence for prior art searches. The SINGER Database includes the following paragraph in its disclaimers: "The contents of this site should not be construed as professional opinion. They are intended for general informational purposes only. The contents may contain technical inaccuracies or typographical errors. The Centres of the CGIAR independently manage the information stored in or made accessible by this site. Users must directly contact the specific CGIAR Centre with questions or comments regarding information managed by that Centre."<sup>19</sup> Efforts are underway to update and standardize data with reference to each accession. Additional background information on SINGER is contained at Annex II of the present document.

23. WIPO and the CGIAR have hyperlinked the SINGER to the WIPO Online Portal of Databases and Registries Concerning TK and Genetic Resources, so as to further this pilot study of mechanisms to assist in identifying relevant prior art relating to TK and genetic resources during patent procedures. Access to SINGER would mean that examiners at patent-granting authorities may discover relevant plant genetic resources which are held in custody by the CGIAR during their prior art searches.<sup>20</sup> Searches of the data held in SINGER could contribute to avoiding the grant of patents for inventions which are based on germplasm held by the CGIAR and which do not fulfil the novelty and inventive step requirements in light of such germplasm as prior art.

### III. CONSIDERATIONS FOR EFFECTIVE DEFENSIVE PUBLICATION STRATEGIES

24. In order for a defensive publication strategy to be effective, the disclosing organization, community or individual should consider certain practical guidelines on how they publish. These guidelines include, for example, clear publication dates, the medium and language of publication, content of the disclosure, availability to the public, timing of publication, and management of rights arising from the publication. Such principles and strategies have already been outlined for several institutions or organizations.<sup>21</sup> The following principles

<sup>19</sup> See < [http://www.singer.cgiar.org/Legal\\_Notice/legal\\_notice.htm](http://www.singer.cgiar.org/Legal_Notice/legal_notice.htm) >.

<sup>20</sup> See Section V.2.2 on the WIPO Portal and on the Internet at < <http://www.wipo.int/globalissues/databases/tkportal/index.html> >.

<sup>21</sup> See for an example in the agricultural sector, Adams, Stephen and Victoria Henson - Apollonio. "Defensive Publishing: A Strategy for Maintaining Intellectual Property as Public Goods." *ISNAR Briefing Paper* No.53. ISNAR, September 2002. In the pharmaceutical bioprospecting context, see Ruiz, Manuel. "The International Debate on Traditional Knowledge as Prior Art in the Patent System: Issues and Options for Developing

summarizes some of the key considerations that may need to be considered by TK holders and custodians of genetic resources:

(a) *Prior informed consent and clarity of objectives:* because defensive protection will often entail either the first publication of TK or information about genetic resources, this may have significant implications for the rights of the TK holders and custodians of genetic resources. For instance, it would mean that TK holders may forego patent rights over any innovation thus disclosed, and it would effectively end the protection of such material under laws concerning trade secrets and confidentiality. For material already publicly available in principle, but in fact obscure and difficult to access, a defensive protection strategy may entail making this material much more readily available – in turn, this may increase the possibility of third parties gaining access to and using this information, potentially in ways that would run counter to the interests and concerns of TK holders. For this reason, it is essential to consider carefully whether defensive protection is really what is intended, and whether the community or institution concerned would actually prefer to pursue a positive protection strategy or a combined positive and defensive approach. It would be important to secure the prior informed consent of any party providing information or material that would be disclosed in a defensive protection mechanism: this consent may need to be based on a full description of the implications of disclosure. Document WIPO/GRTKF/IC/5/5 discusses the development of a toolkit that would assist in dealing with these fundamental questions.

(b) *Unambiguous publication date:* prior art will only be considered relevant to the substantive examination of a patent if it has been made available to the public before the filing date or priority date of the patent application. Therefore, an unambiguous publication date is critical for effective defensive protection. This is particularly relevant for Internet-based publication strategies, where the content of web pages is often changed without clearly dating the amendments. The important date is the date on which the material has been made available to the public, not necessarily the date on which it was first written down (for instance, in the situation where information was kept confidential and only subsequently published). Another important factor is that a patent application with an earlier priority date may be counted as relevant prior art: for instance, even if the earlier application was not published as at the priority date of the later application, it may still be counted as relevant in determining the novelty of the later application. Prior secret commercial use may also be relevant in some countries and in some circumstances. Details of the legal situation in these areas vary considerably between jurisdictions.

(c) *Language and medium of publication:* the cost/effectiveness ratio for defensive publication may vary significantly between various paper-based, print and electronic media. Often governments, organizations or communities seeking defensive protection for their resources and innovations are constrained by cost considerations and must take into account the costs of translation. Stakeholders will probably also have their own preferences as regards

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[Footnote continued from previous page]

Countries.” CIEL, October 2002; and Center for International Environmental Law (CIEL). “Comments on Improving Identification of Prior Art. Recommendations on Traditional Knowledge Relating to Biological Diversity. Submitted to the United States Patent and Trademark Office.” August 2, 1999.

the medium of publication, based on their existing publication instruments.<sup>22</sup> If an Internet-based publication medium is chosen, it is crucial, however, that it be possible to verify that the disclosure has remained consistently available in the same forms since its publication. It is also important (as noted in paragraph (b) above) that the date of publication be clearly established, a point which is not always clear for Internet materials.

(d) *Content of the disclosure:* It is critical for the defensive strategy that the disclosure should contain a complete and comprehensive description of the entire technological concept concerned. If the description covers only certain aspects of the concept, it will be less effective in preventing subsequent patent claims on other aspects of the technological concept. The defensive publications should therefore include descriptions of the use of the technological concept, both the uses which have been shown within TK systems and speculation about other possible uses or applications of the disclosed innovation. The description of a technological concept should also aim at meeting the requirement to enable a person skilled in the art to perform it in practice. If defensive publications include statements indicating that certain innovations, technical approaches or ideas will not work, it may actually strengthen a claim on non-obviousness for a related patent claim that concerns a way of making this technology workable: such statements should therefore be made with caution.

(e) *Availability to the public:* The critical requirement for a specific teaching to form part of the state-of-the-art, is that it must be available to the public. There is considerable case law on what constitutes “availability” and “the public.” Generally, information which is held confidential is not considered prior art. In the case of TK the term “the public” has been particularly scrutinized with respect to the question whether a teaching has been disclosed to “the public” when it has been used in a traditional community, but not outside. The term “availability” becomes important in the genetic resources and TK context with regard to the use of databases and their making available to patent offices exclusively under non-disclosure agreements. This subject is discussed in Section V.2.3 below. Generally speaking, to be counted as prior art, information must have been available to the public: in some cases, this can be as simple as disclosure to one other person, without placing that person under an obligation of confidentiality. In practice, to ensure that it is taken into account during routine search and examination, it is advantageous (from the point of view of defensive protection) if the disclosed information can be easily found by people doing research in the field and especially by patent examiners. On the other hand, making information readily available may well undermine other protection interests (see the extensive discussion in documents WIPO/GRTKF/IC/5/5 and WIPO/GRTKF/IC/5/12).

(f) *Management of rights arising from defensive publication:* While defensive publication is intended to waive any possibility of acquisition of patent rights for the disclosed invention, the defensive publication may itself give rise to other intellectual property rights such as copyright or *suigeneris* rights in non-original databases. These rights should be proactively managed by the disclosing stakeholders. Additionally, there are some forms of defensive publication which may allow the publishing stakeholder to retain certain rights or to

<sup>22</sup> For example, the Gulf Cooperation Council Folklore Center already publishes a Quarterly Review of Folklore in paper form, which includes traditional medicine. In such a case, it would probably be most efficient and cost-effective to build the defensive strategy upon the existing publications.

defer the surrender of the rights. These options as well should be proactively managed and are further addressed in Section V.2.1.

25. In order to provide practical assistance to stakeholders on how to effectively implement such principles, the Committee has produced a Toolkit with the direct input of the concerned stakeholders. This and other products of the Intergovernmental Committee related to defensive protection will now be reviewed.

#### IV. ACTIVITIES AND APPROACHES OF THE COMMITTEE

26. This section reviews the approaches and activities undertaken by the Committee to address the aforementioned concerns about defensive protection of TK and genetic resources. At its first session, the Committee generally supported<sup>23</sup> a work program which included the task “to consider revising existing criteria and developing new criteria which would allow the effective integration of traditional knowledge documentation into searchable prior art (Task B.3).”<sup>24</sup> At its second session, the Committee considered a Progress Report on the Status of Traditional Knowledge as Prior Art<sup>25</sup> and expressed support for the following activities:

(a) to compile an inventory of existing traditional knowledge-related periodicals, which document and disclose traditional knowledge, with a view to discussing a possible recommendation that certain periodicals may be considered by the International Search Authorities for integration into the minimum documentation list under the PCT. (Activity 1)

(b) to study the feasibility of electronic exchange of public domain traditional knowledge documentation data, including through the establishment of international online traditional knowledge databases and digital libraries, taking into account differences in the needs of different stakeholders and the specificity of traditional knowledge in different regions, languages, media and legal contexts. (Activity 4)

(c) to examine the applicability of existing intellectual property documentation standards to traditional knowledge-related subject matter and the relationship of these standards with existing traditional knowledge documentation standards. (Activity 5)

(d) to discuss ways and means of providing assistance to traditional knowledge documentation initiatives to manage the intellectual property implications during the documentation process. (Activity 6)<sup>26</sup>

<sup>23</sup> Regarding the adoption of Task B.3, see paragraph 155, document WIPO/GRTKF/IC/1/13 (“Report”).

<sup>24</sup> For the exposure of Task B.3 see paragraph 80, document WIPO/GRTKF/IC/1/3 (“Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore – An Overview”).

<sup>25</sup> See document WIPO/GRTKF/IC/2/6.

<sup>26</sup> See document WIPO/GRTKF/IC/2/6, Annex III and document WIPO/GRTKF/IC/2/16, paragraph 157.

27. The Committee has since delivered practical outcomes on all these Activities. These deliverables are summarized in Annex I and described in detail in Section VI below. Briefly, the Committee's work has included:

(a) adoption, at its third session, of Inventories of TK -related Periodicals and of TK-related Databases (Activity 1); <sup>27</sup> these inventories were forwarded to, and are being processed by, the relevant subsidiary bodies of the PCT; <sup>28</sup>

(b) consideration, at its fourth session, of Technical Proposal on Databases and Registries of Traditional Knowledge and Biological/Genetic Resources, <sup>29</sup> which facilitate the electronic exchange of documentation data (Activity 4) and apply existing IP documentation standards, such as WIPO Industrial Property Documentation Standard ST.9, <sup>30</sup> to TK and genetic resources (Activity 5); <sup>31</sup> and

(c) adoption, at its fourth session, of an outline of a draft Toolkit for IP Management When Documenting TK and Genetic Resources, <sup>32</sup> which will assist documentation initiatives to manage the IP implications of their work, thereby implementing Activity 6. <sup>33</sup>

28. Thus all adopted Activities for the implementation of Task B.3 have been completed or are in the final stages of being discharged. These activities share some common general features:

(a) *Complementarity of Positive and Defensive Protection* : Since its first session, the Committee has emphasized that defensive and positive legal protection are two complementary aspects of providing appropriate IP protection for TK and genetic resources. This complementarity was reflected in the initial terms of reference of the Committee, as adopted by the WIPO General Assembly. <sup>34</sup> Committee participants have stressed in various statements and working documents that positive and defensive protection are inseparable parts of providing adequate protection for TK and genetic resources. <sup>35</sup> In the Committee's technical work on practical mechanisms, this complementarity is reflected in the documentation toolkit. <sup>36</sup>

(b) *Integrated approach to defensive protection of TK and genetic resources*: Committee participants have emphasized the importance of taking an integrated approach to

<sup>27</sup> See document WIPO/GRTKF/IC/3/5 and WIPO/GRTKF/IC/3/6.

<sup>28</sup> See Section V.1.1 below.

<sup>29</sup> See document WIPO/GRTKF/IC/4/14.

<sup>30</sup> WIPO Industrial Property Documentation Standard ST.9 is entitled 'Recommendation Concerning Bibliographic Data On and Relating to Patents and SPCs.'

<sup>31</sup> See Section V.2.5 below.

<sup>32</sup> See document WIPO/GRTKF/IC/4/5.

<sup>33</sup> See Section V.2.1 below.

<sup>34</sup> See documents WO/GA/6/26 and WO/GA/6/29.

<sup>35</sup> See document WIPO/GRTKF/IC/4/14: "Databases and Registries should achieve multiple IP objectives in respect of the genetic resources and TK on which they contain information. These objectives included defensive and positive legal protection in respect of the contents of the databases and registries. The full range of proposed objectives is set out in the Appendix of the Annexure to the present document." (Annex, page 2).

<sup>36</sup> See document WIPO/GRTKF/IC/5/5.

genetic resources and TK as a continuity of subject matter which should be covered in an integrated manner by defensive protection measures. This approach is given effect in the Technical Proposal on Databases and Registries of TK and Biological/Genetic Resources, which was submitted to the Committee.

37

(c) *Combination of Practical Tools and Policy Development:* The Committee discussed defensive protection both through legal norms and their operation and through practical capacity - building.<sup>38</sup> While the Committee dealt with these two aspects in an integrated fashion, in the interest of clear presentation they are covered distinctly in Sections V.1 and V.2 below.

## V. WIPO DELIVERABLES ON DEFENSIVE PROTECTION

29. The deliverables produced by the Committee can be classified as:

- amendments to international patent systems that are administered by WIPO. These amendments rely upon changes to rules and systems established by international IP treaties; and
- practical products and tools for stakeholders. These tools do not amend existing systems, but allow TK holders and custodians of genetic resources to use these systems more effectively for their purposes.

### V.1 Revision of WIPO -administered Patent Systems

30. The Committee has taken an active approach to the revision of existing patent systems in order to further improve the defensive protection of TK and genetic resources. The Committee has facilitated such revisions by undertaking conceptual groundwork and by producing elements which could be used by the competent WIPO bodies to make and implement such amendments. This line of work has focused on two WIPO -administered treaties, namely the Patent Cooperation Treaty (PCT) and the Strasbourg Agreement Concerning the International Patent Classification (IPC).

#### *V.1.1 Revision of the Minimum Documentation under the Patent Cooperation Treaty*

31. The Patent Cooperation Treaty (PCT) is a WIPO -administered treaty for international cooperation in the field of patents. One international patent application under the PCT can have the legal effect of simultaneously filing applications in a large number of countries throughout the world. Importantly, from the point of view of the current document, the PCT provides for international coordination with regard to the filing, searching and examination of patent applications and the publication of technical information contained therein. The PCT simplifies and reduces the cost of obtaining patent protection and facilitates public access to a wealth of technical information relating to inventions, including in the field of TK and genetic resources. The international search and examination processes also have significant effect for defensive protection strategies.

<sup>37</sup> See document WIPO/GRTKF/IC/4/14.

<sup>38</sup> See document WIPO/GRTKF/IC/5/12, paragraphs 12 to 15.

*PCT Minimum Documentation*

32. Article 15(4) of the PCT provides that in the context of international searches “[t]he International Searching Authority... shall endeavor to discover as much of the relevant prior art as its facilities permit, and shall, in any case, consult the documentations specified in the Regulations.” The “documentations specified in the Regulations” is specified in Rule 34 of the Regulations Under the PCT and is generally referred to as the PCT minimum documentation. Rule 34 provides that the minimum documentations shall include certain national patent documents, as specified in the Regulations, the published international applications, the published regional applications for patents and inventors’ certificates, the published regional patents and inventors’ certificates, and “such other published items of non-patent literature as the International Searching Authorities shall agree upon and which shall be published in a list by the International Bureau when agreed upon for the first time and whenever changed.”<sup>39</sup>

33. Currently the International Searching Authorities have agreed that, for the purposes of this Rule, the published items of non-patent literature to be included in the minimum documentations should be the items published in 134 periodicals during the five-year period preceding the time at which the international search report is established.<sup>40</sup> It is understood that the International Searching Authority would not be precluded from consulting issues of these publications published prior to the beginning of this five-year period.

34. In the PCT International Search Guidelines the international search documentation is defined as “a document collection that is systematically arranged (or otherwise systematically accessible) for search purposes according to the subject matter content of the documents, which are primarily patent documents supplemented by a number of articles from periodicals and other items of non-patent literature.”<sup>41</sup>

35. The minimum documentation is updated periodically and the present list was agreed upon by the International Searching Authorities (ISA) by correspondence in September 2001, with effect from September 1, 2002. As a possible measure to improve the availability of traditional knowledge-related NPL in the context of international searches the Committee recommended the integration of periodicals, gazettes and newsletters which document traditional knowledge into the minimum documentation list. The work of the Committee to facilitate such an integration is described in the following sections.

*Development of the Inventories*

36. At its second session, the Committee agreed on the compilation of a non-exhaustive Inventory of Traditional Knowledge-related Periodicals<sup>42</sup> and a non-exhaustive Inventory of Traditional Knowledge-related Databases.<sup>43</sup> This was done with a view to discussing possible recommendations for the integration of certain periodicals into the minimum documentation

<sup>39</sup> Rule 34.1(b)(iii) of the Regulations Under the PCT.

<sup>40</sup> See “Minimum Documentation” Under Rule 34.1(b)(iii) of the Regulations Under the PCT in *PCT Gazette* of 27 March 2003 (S-02/2003).

<sup>41</sup> Paragraph IX-2.1, PCT International Search Guidelines (as in force from 18 September 1998).

<sup>42</sup> See document WIPO/GRTKF/IC/3/5, especially Annex I.

<sup>43</sup> See document WIPO/GRTKF/IC/2/6, paragraph 81.

list under the PCT. <sup>44</sup> The inventories were compiled through the research of the Secretariat and through responses to a “Request for References” that was sent by the Secretariat to Committee participants, Indigenous Knowledge Resources Centers, National Libraries and Museums, and other counterparts with potentially useful information, such as participants in the WIPO Fact Finding Mission on Intellectual Property Needs and Expectations of Traditional Knowledge Holders carried out by WIPO in 1998 and 1999. In total, over 300 “Requests for References” were sent directly to a wide variety of governments, organizations, communities and individuals. In addition, the “Request for References” was disseminated by the CBD Secretariat through the CBD Clearing-house Mechanism <sup>45</sup> and a Biodiversity communication network maintained by UNEP, and was submitted to the CBD Ad hoc Open-ended Intersessional Working Group on Article 8(j) and Related Provisions.

37. At its third session, the Committee expressed support for the work carried out by the Secretariat in drawing up the Inventories and requested that, for its fourth session, the Secretariat should prepare a short report setting out subsequent activities relating to these Inventories. In document WIPO/GRTKF/IC/3/5, the Secretariat suggested five possible activities relevant to future uses of the non-exhaustive Inventory of Traditional Knowledge related Periodicals. Possible Activity I provided the following:

The Committee may wish to submit this document [i.e., WIPO/GRTKF/IC/3/5] together with Annex I and Annex II to the Patent Cooperation Treaty’s Committee for Technical Cooperation (PCT-CTC) for consideration by the International Searching Authorities with a recommendation that certain periodicals listed in the Inventory of existing traditional knowledge-related Periodicals at Annex I be considered for integration by the International Search Authorities into the minimum documentation list under the PCT. <sup>46</sup>

38. Following Committee discussion, the Chair concluded that all government delegations and representatives of intergovernmental organizations had either explicitly supported all the five proposed activities or they had not opposed them. <sup>47</sup> The Chair further noted certain specific observations that should be taken into account when implementing these activities.

#### *Integration of the Inventories*

39. Pursuant to the decision of the Committee, the Secretariat submitted a working document entitled “PCT Minimum Documentation” to the twentieth session of the PCT’s Committee for Technical Cooperation (PCT/CTC). <sup>48</sup> The document described developments in two areas which may have an impact upon the definition of the PCT minimum documentation and may require reconsideration by PCT/CTC, in particular concerning :

- TK-related periodicals and databases, and

<sup>44</sup> See documents WIPO/GRTKF/IC/2/17 (“Report”), paragraph 157, and WIPO/GRTKF/IC/2/6, paragraph 81.

<sup>45</sup> See < <http://www.biodiv.org/programmes/socio-eco/traditional/references.asp>>.

<sup>46</sup> See document WIPO/GRTKF/IC/3/5, paragraph 13(a).

<sup>47</sup> See document WIPO/GRTKF/IC/3/17 (“Report”), paragraph 157.

<sup>48</sup> See document PCT/CTC/20/4.



- the use of databases in certain technical fields, as a supplement to paper-based non-patent literature specified in the PCT minimum documentation.

40. Regarding the TK-related Inventories, the document proposed that the PCT/CTC recommend to the Assembly of the PCT Union, that the Meeting of International Authorities under the PCT (PCT/MIA), which comprises all International Searching Authorities and International Preliminary Examining Authorities, should study this matter at its next session.<sup>49</sup> It further recommended that the PCT/MIA give a recommendation to the PCT/CTC on proposed modifications of PCT Rule 34<sup>50</sup> and proposed mechanisms for reviewing and maintaining the non-patent literature part of the PCT minimum documentation.

41. At its twentieth session, the PCT/CTC made the above mentioned recommendation and the PCT Assembly.<sup>51</sup> At its thirty-first session, the Assembly of the PCT Union took note of the unanimous recommendation of the PCT/CTC, and requested the PCT/MIA to undertake the study proposed in document PCT/CTC/20/5, and to make recommendations to the PCT/CTC on proposed modifications of Rule 34 and proposed mechanisms for reviewing and maintaining the non-patent literature part of the PCT minimum documentation.<sup>52</sup>

42. Accordingly, at the seventh session of the PCT/MIA, the Inventories produced by the Intergovernmental Committee were considered by all International Searching Authorities and International Preliminary Examining Authorities of the PCT as a supplement to paper-based non-patent literature specified in the PCT minimum documentation.<sup>53</sup> The PCT/MIA agreed that “an appropriate selection of periodicals from the inventory should be made with a view to including periodicals containing articles with descriptions of disclosed traditional knowledge to a sufficiently practical or technical level that they would be of relevance to patent examiners carrying out prior art searches.”<sup>54</sup> The Meeting also agreed on a non-exhaustive list of criteria which should be used in the selection of appropriate periodicals from the inventory. This list includes the following criteria:

- (i) sufficient description of technical content so as to qualify as prior art, including ability to ascertain prior art date;
- (ii) practicable access to periodicals, including their availability in electronic form;
- (iii) availability of an English text of articles or, at least, of English-language abstracts;
- (iv) the range of fields of technology covered by periodicals;
- (v) geographical context of periodicals; and
- (vi) access conditions applicable to periodicals, including cost and text searchability.<sup>55</sup>

<sup>49</sup> See PCT/CTC/20/4, paragraph 10.

<sup>50</sup> PCT Article 15(4) states that “[t]he International Searching Authority [...] shall endeavor to discover as much of the relevant prior art as its facilities permit, and shall, in any case, consult the documentations specified in the Regulations.” PCT Rule 34 (“Minimum Documentation”) contains the definition of the documentation referred to in Article 15(4).

<sup>51</sup> See document PCT/CTC/20/5 (“Report”), paragraph 10.

<sup>52</sup> See document PCT/A/31/10 (“Report”), paragraph 54.

<sup>53</sup> See document PCT/MIA/7/3 (“PCT Minimum Documentation”).

<sup>54</sup> See document PCT/MIA/7/5, paragraph 11.

<sup>55</sup> Ibid., paragraph 12.

43. The PCT/MIA furthermore agreed to revisit this matter at its next session. In order to compile comprehensive material for its consideration, it requested the Secretariat to issue a circular to the members of PCT/CTC inviting them to evaluate the Inventory and to suggest a selection of appropriate periodicals from the Inventory, or other TK-related periodicals. The PCT/MIA added that members of PCT/CTC should also be invited to investigate alternative ways for providing access to traditional knowledge documentation, for example, by using databases that exclusively or partly contained relevant traditional knowledge data.<sup>56</sup> The next meeting of the PCT/MIA took place from May 5 to 9, 2003, and a report on the outcome of the PCT/MIA's discussions on the integration of certain periodicals from the Inventories may be provided to the Committee at its fifth session.

#### *V.1.2 Revision of the International Patent Classification*

44. The International Patent Classification (IPC) is a classification system that assists in searching patent documents according to the field of technology they cover. It is based on the WIPO-administered Strasbourg Agreement Concerning the International Patent Classification, which was concluded in 1971 and entered into force in 1975. The Agreement is open to States party to the Paris Convention; it currently has 53 adherents. In practice, many more countries actually apply the IPC: industrial property offices of approximately 100 countries and five organizations allot IPC symbols to the patent documents they issue, amounting to more than million documents each year. Altogether some 25 million patent documents were provided with the classification symbols of the IPC.

45. The IPC has been developed primarily as a system for classification, and later retrieval, of patent documents. During nearly 30 years of practice, the IPC has been found a very useful tool for the prior art search for R&D activities, for the novelty and patentability search conducted by industrial property offices with respect to their patent examination procedures, and for the legal status search to obtain information on the validity of a patent or a published patent application on a given date. The IPC is also more and more broadly applied for classifying technical patent-associated literature and has the prospect of becoming an universal classification for scientific, technical and patent information.

#### *WIPO Task Force on Classification of Traditional Knowledge*

46. Since the role of intellectual property in the protection, dissemination and utilization of traditional knowledge has received increasing attention in recent years, the importance of documentation and information aspects of traditional knowledge is also increasingly acknowledged. At the thirtieth session of the Committee of Experts of the IPC Union, held in February 2001, the Delegation of India made a presentation of the governmental project for establishing a Traditional Knowledge Digital Library relating to traditional Indian medicine and explained the structure of the Traditional Knowledge Resources Classification (TKRC) developed for providing efficient access to traditional knowledge data. The Committee agreed that TKRC should be studied in detail with a view to investigating its information aspects and its relationship to the IPC and decided to create, to this end, a WIPO Task Force on Classification of Traditional Knowledge. The Committee appointed the International Bureau of WIPO as coordinator of the Task Force<sup>57</sup>. The Committee agreed that the mandate

<sup>56</sup> Ibid., paragraph 13.

<sup>57</sup> See document IPC/CE/30/11, paragraphs 47 to 53.

of the Task Force would be to elaborate advice on the future development of TKRC, in particular with a view to its expansion to documentation of other countries, and the investigation of how its proper relationship to the IPC should be established.

47. The report of the Task Force was submitted to the Committee of Experts at its thirty-first session, which took place from February 25 to March 1, 2002. The Committee agreed with the conclusion of the Task Force that the most efficient way of developing classification tools for traditional knowledge would be their integration into the IPC. The Committee noted that the IPC, representing the worldwide system for classifying patent information, could also be successfully applied for classifying non-patent documentation, such as traditional knowledge documentation. However, only a few entries in the IPC were available for classifying this subject matter, and substantial revision of the Classification could be required in this regard.

48. The Committee instructed the Task Force, accordingly, to continue its work and to start preparation of an IPC revision proposal with regard to classification of traditional knowledge documentation. The Committee indicated that, in view of the urgency of the matter, it would be highly desirable that the revision results were available already in the next edition of the IPC, which will enter into force on January 1, 2005.

#### *Development of the IPC Revision Proposal*

49. At its thirty-second session, held from February 24 to 28, 2003, the Committee of Experts noted that a revision proposal relating to the creation of the new main group A61K36/00, with approximately 200 subgroups, in the field of medicinal preparations containing plants had been prepared by the Task Force and that this proposal had been included in the IPC Revision program as a new revision project.

50. The Committee confirmed its instruction to the IPC Revision Working Group to complete the revision project relating to traditional medicine classification in time, in order to make the results available in the next edition of the IPC.

51. The Committee agreed with the suggestion of the Task Force that a more detailed revision could be carried out at a later stage, in the course of the next IPC revision period

58.

#### *Future Development of the IPC in the TK-Related Fields*

52. The Committee instructed the Task Force to continue its work on further development of classification tools for traditional knowledge and to investigate possible patent classification aspects relating to components of biodiversity and folklore and requested the Task Force to consider how the future revised IPC could be linked to traditional knowledge resources classifications which may be developed in various countries, and how to best organize access to traditional knowledge documentation which was in public domain, including hyperlinking the IPC to traditional knowledge databases.

53. A work progress report will be submitted by the Task Force to the Committee at its next session which is scheduled to take place from October 6 to 10, 2003.

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<sup>58</sup> See document IPC/CE/32/12, paragraphs 83 to 91.

## V.2 Practical Products and Tools for Stakeholders

54. These second category of outcomes produced by the Committee is a package of practical tools and products for the defensive protection of TK and genetic resources. These products include a Toolkit for IP Management, an Online Portal of Registries and Databases of TK and Genetic Resources, a sampled database of Ayurvedic traditional medicine from South Asia, a Questionnaire on Databases and Registries of TK and Genetic Resources, and Technical Proposals Concerning Databases and Registries of TK and Biological/Genetic Resources. Each of these products is reviewed in detail in the following sections.

### *V.2.1 Toolkit for IP Management*

55. At its third session, the Committee decided to develop a “Toolkit for IP Management When Documenting TK and Genetic Resources” in order to assist stakeholders in managing the IP implications of their documentation work.<sup>59</sup> The Toolkit is of a practical and applied nature and is not intended to suggest any particular approach as mandatory or even recommended. It does not suggest an exclusive focus on defensive protection. Rather, the Toolkit takes an integrated approach to positive and defensive protection strategies. It is organized in practical terms around the documentation process. It is intended to describe legal tools that are available, to discuss how they can be successfully used and thereby to enable informed choices by TK holders themselves. The aim is to allow stakeholders to determine whether, and in what cases, IP rights are the appropriate legal and practical mechanisms to achieve their objectives concerning their TK and genetic resources. Defensive protection strategies are an important example, but by no means the only example, of such tools.

56. The Toolkit is structured according to the three phases of most documentation projects, so as to illustrate the diverse IP issues that arise at each stage of documentation:

- *Before* documentation, creating awareness and setting objectives;
- *During* the documentation process, practical management of IP issues; and
- *After* documentation, options for the acquisition, exercise and enforcement of IP rights, and other protection mechanisms.

57. While the principal objective focuses on the needs and interests of TK holders and custodians of genetic resources, the Toolkit is also addressed to a wide range of stakeholders, with the aim of promoting cooperation between these various parties. It is important to emphasize that the Toolkit does:

- Not suggest that TK should be put into the public domain;
- Not provide a full introduction to IP law and practice, nor substitute for specific legal or technical advice on whether individual elements of TK and genetic resources can or should be protected by IP rights;
- Not propose or assess options for legislative action on TK or genetic resources, or interpret legislation;

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<sup>59</sup> See document WIPO/GRTKF/IC/3/17, paragraph 157.

- Not provide advice on protection for TK and genetic resources beyond national legal systems; and
- Not advise on collecting genetic or biological resources.

58. In addition, the Toolkit does not cover traditional cultural expressions, as such, which have been protected by national law on copyright and related rights, and in some cases *suigeneris* folklore protection. The toolkit will be drafted so as to complement, and as appropriate refer to, the forthcoming “WIPO Practical Manual for the Legal Protection of Traditional Cultural Expressions.”<sup>60</sup>

59. The Toolkit was developed with widespread stakeholder involvement, starting in 1998 during the WIPO Fact-finding Missions and ending with systematic consultations on the draft Toolkit in 2002-2003.<sup>61</sup> The next steps in the development of the Toolkit will include the following four stages: consultations, field-testing, translation, and dissemination. The most important prerequisite for an effective and balanced toolkit is that all stakeholders have been fully consulted and their comments taken into account, especially TK holders and custodians of genetic resources themselves. The Secretariat has carried out extensive consultations with a diverse range of stakeholders and is continuing to seek wide-ranging input. The support of the Committee participants is solicited in facilitating consultations at the national, regional and local levels on the toolkit. After a thorough consultation process, the toolkit will be ready to be field-tested by communities, organizations and institutions which are documenting TK and genetic resources.

#### V.2.2 Online Portal of Registries and Databases

60. It is to be emphasized that WIPO does not promote the establishment or use of databases or registries for the protection of TK and genetic resources. Numerous countries and communities have, however, at their own initiative compiled databases or registries of genetic resources and TK over many years. At the request of Member States, WIPO has facilitated international discussion about how these approaches can be best used to advance the IP-related interests of the custodians of TK and genetic resources. At the second session of the Committee, several Committee members requested to learn from the experiences of those countries which had already established databases and registries.<sup>62</sup> In order to facilitate such an information exchange between Committee participants, the Secretariat created an “Online Portal of Databases and Registries Related to TK and Genetic Resources” on the WIPO website, to which a number of databases are hyperlinked. The hyperlinked databases can be accessed, viewed and studied by Committee participants through the WIPO Portal at: <<http://www.wipo.int/globalissues/databases/tkportal/index.html>>.

61. The databases which are hyperlinked, in part or in total, to the WIPO Portal had been created, maintained, operated and managed by the Member States or international organizations, who have linked samples of the databases to the WIPO Portal. Therefore,

<sup>60</sup> See document WIPO/GRTKF/IC/5/3.

<sup>61</sup> The need for such a toolkit was initially expressed during the WIPO Fact-finding Mission on IP Needs and Expectations of Traditional Knowledge Holders; see WIPO Fact-finding Mission Report, p. 249.

<sup>62</sup> See the statements of New Zealand (138), Republic of Korea (135), Russia (140), United States of America (134) and Venezuela (122) in document WIPO/GRTKF/IC/2/16.

WIPO makes no representation or warranties regarding (samples of) the databases which are hyperlinked to the Portal, including as to the correctness, reliability, accuracy, currency, completeness or correct translation into the English language of the databases or samples thereof. WIPO also makes no warranties with respect to the existence of consent of third parties, including prior informed consent by TK holders and custodians of genetic resources, the consent of which may be required for the use, incorporation or publication of the data in the databases or samples thereof.<sup>63</sup> The (samples of) databases on the WIPO Portal may, however, provide useful examples which allow for the study of IP issues arising in the establishment and management of such databases and registries.

62. At its seventh session, held from February 10 to 14, 2003, the Meeting of International Authorities under the PCT (PCT/MIA) was informed of the creation of the Online Portal and, after consideration of the established work done by the Committee, the MIA reached the following conclusions:

The Meeting was... informed that the Intergovernmental Committee had established a Portal of Online Databases for such initiatives and felt that this could provide an appropriate format to facilitate electronic access to periodicals and other information resources about disclosed traditional knowledge. The Meeting agreed that the expansion of the PCT minimum documentation to include traditional knowledge documentations should be coordinated with, and take into account, these initiatives. In view of the interest expressed in ensuring practical access to such material for search purposes, one possibility would be to create, in the context of the PCT, a similar but distinct portals specifically for international searches, which may, for instance, give access to any relevant on-line periodicals included within the PCT minimum documentation as well as other related traditional knowledge information.<sup>64</sup>

63. In light of these conclusions by other relevant WIPO fora, the current Online Portal may provide a starting point and building block for future similar Portals to be created by the SCIT or the PCT subsidiary bodies. Most recently SINGER has been added to the Portal and further databases may be added in the future. Furthermore, at the request of the Government of India, the WIPO Secretariat developed a test database in order to test the effectiveness of online databases as a tool for defensive protection.

### *V.2.3 Sample Databases of Disclosed Traditional Medicine*

64. The WIPO work on databases and registries is guided by certain principles which have been developed by Member States to guide the WIPO work in this area. These principles include:

- The purpose of Databases and Registries is not to put undisclosed TK and genetic resources into the public domain;
- Databases and Registries should achieve multiple IP objectives in respect of the genetic resources and TK on which they contain information. These objectives

<sup>63</sup> See the complete "Terms of Use" applicable to the WIPO Portal and the (samples of) databases linked with it, at < <http://ipdl.wipo.int/en/search/tkdl-terms.html>>.

<sup>64</sup> See document PCT/MIA/7/5 ("Report"), paragraph 14.

included defensive and positive legal protection in respect of the contents of the databases and registries. The full range of proposed objectives is set out in the Appendix of the Annexure to document WIPO/GRTKF/IC/4/14;

- The rights of the custodians of TK and genetic resources to their continuing control and enjoyment of their knowledge and resources are to be recognized throughout the compilation, operation and use of databases and registries;
- Databases and Registries can be used as a set of tools when documenting TK and associated genetic resources with appropriate mechanisms to restrict access in accordance with the requirements of the custodians and traditional owners;
- Strategic IP management is critical when documenting TK and genetic resources, as are measures for ensuring prior informed consent concerning documentation and subsequent use of TK and associated genetic resources;
- There is a need to address and manage the risks attached to compilation and digitization of TK, which may lead to the ready access and unauthorized exploitation of the TK, in the absence of clear international legal principles; and
- The teaching of TK systems may differ from the teaching of modern science even when it concerns identical practical solutions to technical problems in the same field of technology, utilizing the same biological/genetic resource. There is a need to develop practical means of integrating the relevant teachings of TK systems and modern science when determining inventive step during the substantive examination of patent applications which claim TK-related inventions.<sup>65</sup>

65. The development and use of multi-purposed databases which serve both defensive and positive protection of TK and genetic resources has therefore been recommended as the next step in WIPO's work in this area. Upon request from its Member States and in accordance with these guidelines, WIPO has provided the assistance to its Member States on developing databases of TK and genetic resources. One online database, which is linked to the Portal and was expressly established by the Secretariat at the request of the Indian Government, is described in detail in the following section.

#### *Health Heritage Test Database*

66. At the request of the Government of India, the WIPO Secretariat assisted the Council of Scientific and Industrial Research (CSIR) of India in making available an online database which the CSIR had previously published on CD-ROM. This database, entitled "Health Heritage Test Database," contains non-patent and patent literature on fifty medicinal plants endemic to South Asia and on their traditional uses in the codified knowledge systems of traditional medicine in South Asia. It also includes the vernacular names of the medicinal plants in 22 South Asian languages. The database focuses on the Ayurveda system of traditional medicine. The most important feature of the Ayurveda traditional knowledge system from an intellectual property point of view is that it was codified and disclosed in writing in ancient Sanskrit scriptures in the 12<sup>th</sup> century B.C. This knowledge is therefore

<sup>65</sup> See document WIPO/GRTKF/IC/4/14, Annex, page 2.

clearly and unambiguously in the public domain and forms part of prior art in the field of traditional medicine. It is common knowledge for most people in the region. It does not pose the complex questions which arise in the context of indigenous and tribal medicine which has been kept undisclosed by individual healers or communities.

67. The database was compiled by the “Unit for Research and Development of Information Products” (URDIP), a member institution of the Indian Council of Scientific and Industrial Research (CSIR). The traditional knowledge documentation data on the “Health Heritage” CD-ROM was then compiled into an online database by the Intellectual Property Digital Libraries (IPDL) Team and the Traditional Knowledge Division of WIPO. The objective of the database is to provide a trial product against which the perceived potential of databases in making traditional knowledge available as searchable non-patent literature can be tested in practice by patent examiners.

68. The database allows for free text searching of the data by using the PCT Search Engine to search the database, including three different Search Pages, which allow for complex and nested Boolean searches, field searching, phrase searching, right truncation and stop words. These search and retrieval of traditional knowledge data from this database therefore differ from IPC-based prior art searches, which are possible in the Chinese database.<sup>66</sup> The data on the fifty medicinal plants are provided in seven fields.<sup>67</sup> This set of fields follows the structure by which the data were represented in the original CD-ROM of URDIP. The database contains references to modern scientific research work published during 1961 to 2000 on the medicinal plants. It summarizes the chemical studies of plants and biological evaluation of total extracts and fractions thereof. It also lists all the pharmacological, biological and clinical work done on constituents obtained from plants and it gives the complete structures of any new substances isolated.

#### *Use of TK Databases by National Patent Offices*

69. Several online databases or search tools have been created with the intention of making them available to patent-granting authorities for the purpose of prior art searches, in some cases under non-disclosure agreements. This raises some specific practical and policy issues: on the one hand, the search process needs to disclose prior art that can be cited against the claimed invention where relevant; on the other hand, there are concerns that database initiatives may have the effect of making TK and other material much more readily available, thus increasing the likelihood it will be used (even if not patented) by third parties. In some cases, the database or search tool will have the effect not of putting information in the public domain, but making it in practice more accessible to the searcher or examiner: for instance,

<sup>66</sup> Most of the information contained in the database would fall into class A61K of the International Patent Classification (IPC), entitled “Preparations for Medical, Dental, or Toilet Purposes.”

<sup>67</sup> Those fields are the following:

1. Biological Activity
2. Chemical Constituents (CC),
3. Medicinal Properties (MP),
4. Patents (PAT),
5. Other Industrial Uses (OI),
6. Taxonomy (TAX), and
7. Vernacular Names (VN).



when the information is in a less well-known language or is difficult to access in practice. In this case, access to the database itself for the search tool may be restricted, since it would simply facilitate access in turn to the information that is already available to the public by other, less ready means.

70. This section discusses a number of such practical issues that arise when access to a TK database is given to a national patent office are briefly identified in this section. This section pertains only to situations where holders of TK choose to record their TK in a searchable form (i.e. an indexed document or electronic database) and consider giving that database to patent examiners for use in the patent examination process.

(i) *What is the effective date of the TK as a printed publication:* Patent examiners must identify the date that a written reference was “publically” available or publically used to fix the date from which inventions may be anticipated (and patentability precluded) by that reference. The date a TK database is available as prior art may be quite recent. If the database translates other publically available documents, the publication date of those documents may be relevant dates of prior art that is different from the date the database was made available.

(ii) *Where and when was the TK publically used:* When TK is cited as a public use rather than as a publication, the location of that use may affect its availability as prior art. The data upon which such public use occurred will also be relevant.

(iii) *How does the TK relate to standards of inventiveness or obviousness:* To evaluate inventiveness or obviousness, an examiner would consider whether the disclosed TK would have made the claimed invention obvious to a person of ordinary skill in the art at the time the claimed invention was made. TK holders should consider how their disclosed TK might be used in such an analysis.

(iv) *Who has access to the TK database and the underlying TK:* Examiners must ordinarily provide copies to applicants of prior art on which they rely to reject a claimed invention. When a TK database and the TK itself are the same in terms of disclosure content, the database provides a transparent portal to the TK. The disclosure in searchable databases, however, could be different in scope than the TK. Would examiners need to send copies of the database information to the applicants? Would the database information and the underlying TK uses or publications be available to applicants? Could those writing patent applications obtain access to the database to search for prior art before filing their patent applications?

(v) *Is the disclosure content sufficient to teach or suggest the claimed invention:* Prior art disclosures must usually be sufficiently detailed and understandable to “enable” a person of ordinary skill in the claimed technology to practice the claimed invention.

(vi) *Could a TK database have inventorship implications:* Patent examiners are required to assume that inventorship has been correctly identified. They can challenge inventorship only if they have some tangible information that would suggest an error was made. Use of a TK database to raise an inventorship issue may be affected by its availability to applicants.

#### V.2.4 Questionnaire on Registries and Databases (Q.4)

71. At its third and fourth sessions, the Committee decided to undertake an information gathering on the objectives, functionalities and technical specifications of databases and registries for TK and genetic resources.<sup>68</sup> Consequently, the Secretariat issued a questionnaire (WIPO/GRTKF/IC/Q.4) following the fourth session of the Committee. The questionnaire aims to gather information from all relevant stakeholders on the objectives, functionalities and technical specifications of databases and registries relating to TK and genetic resources. This information will be compiled:

(a) to achieve a comprehensive identification of the needs, objectives and priorities which all stakeholders attach to such databases and registries; and

(b) to compile experiences and lessons learned by those stakeholders who have already established and operated such databases and registries.

72. The questionnaire consists of two separate sets of questions, which are directed at two distinct groups: one set of questions (contained in Annex A of WIPO/GRTKF/IC/Q.4) contains questions addressed to stakeholders who have *not* established databases or registries, but who are interested in using or creating a database or registry. These questions aim at assessing their needs and expectations. A second set of questions (contained in Annex B) contains questions addressed to those stakeholders who *have* already established databases and registries, or are in the process of establishing them. These questions gather factual information about existing databases/registries and practical lessons learned by stakeholders during the establishment of the database/registry.

73. An update on responses received to this questionnaire will be provided by the Secretariat at the fifth session during the introduction of Agenda Item 5 of the Draft Agenda.<sup>69</sup> Since the validity of results from such information gathering depends on the number and scope of received responses, it is imperative that as many Committee participants and other stakeholders as possible complete the Questionnaire. The Questionnaire can be retrieved and completed online at < <http://www.wipo.int/globalissues/questionnaires/ic-q4/index.html>>.

#### V.2.5 Technical Proposal on Registries and Databases

74. At its fourth session, the Committee considered certain technical proposals on databases and registries of TK and genetic resources, which proposed technical standards for such mechanisms and identified areas for future work.<sup>70</sup> The proposals were submitted by the Asian Group, based on extensive experiences in Asian countries with the use of registries and databases and based on a synthesis of these experiences achieved at a WIPO Asia-Pacific Regional Seminar on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, held in November 2002.<sup>71</sup>

<sup>68</sup> See document WIPO/GRTKF/IC/4/15 (Report), paragraph 125(i).

<sup>69</sup> See document WIPO/GRTKF/IC/5/1 Prov.

<sup>70</sup> See document WIPO/GRTKF/IC/4/14.

<sup>71</sup> See document WIPO/IPTK/COK/02/1 Prov.

75. The document states that “there is a need to develop an internationally agreed Data Specification (a set of agreed standards) for databases and registries of TK and biological/genetic resources, including the consideration of related legal questions, such as the relationship of documented TK and recognition of rights associated with TK, and the possibility of creating a legal presumption of ownership on the part of the TK holder with a TK rights system.”<sup>72</sup>

76. Responding to this need, the document therefore contains a proposal for a new Task of the Committee. The document specifies that “the objectives of the proposed Task is to develop and recommend a Data Specification (a set of agreed standards) that could be used by databases and registries of TK and associated biological/genetic resources.”<sup>73</sup>

77. The document contains a Draft Data Specification which the Asian Group put forward as a foundation for the Committee to adopt an international data standard for registries and databases of TK and genetic resources.<sup>74</sup> In particular the document proposes the following work of the Committee:

“The Intergovernmental Committee should create a Task in its work program to further develop and adopt the draft Data Specification for Databases and Registries of TK and genetic resources contained in the Annexure. After adopting the draft Data Specification, the Committee should forward the final Data Specification to the Standing Committee on Information Technologies (SCIT), in particular its Standards and Documentation Working Group (SDWG), for consideration as an additional WIPO Industrial Property Documentation Standard and for inclusion in the WIPO Industrial Property Documentation Handbook. As part of the Task, the Committee should consider related legal questions, such as the relationship of documented TK and recognition of rights associated with TK, and the possibility of creating a legal presumption of ownership on the part of the TK holder with a TK rights system.”<sup>75</sup>

78. At its fourth session, the Committee considered document WIPO/GRTKF/IC/4/14 and, following the deliberations of the Committee members, the Chairman concluded, and the Committee decided, that the proposals “would remain on the agenda for the fifth session, including the proposal of the Asian Group set out in paragraph 3.2 of document WIPO/GRTKF/IC/4/14.”<sup>76</sup> Pursuant to this decision, the Committee may wish to return to these proposals.

## VI. POSSIBLE FUTURE DIRECTIONS

79. Since defensive protection was an initial focus of the Committee’s work, a range of products and services in this domain have been delivered by the Committee, and passed on to other relevant WIPO bodies for further implementation. This has essentially discharged the Committee’s initial work programme on defensive protection. Patent disclosure mechanisms

<sup>72</sup> See document WIPO/GRTKF/IC/4/14, Annex, page 3, Section 3.1.

<sup>73</sup> See document WIPO/GRTKF/IC/4/14, Annex, page 5, Annexure, Section I ‘Task Objectives’.

<sup>74</sup> See document WIPO/GRTKF/IC/4/14, Annexure to the Annex.

<sup>75</sup> See document WIPO/GRTKF/IC/4/14, Annex, page 4, Section 3.2, paragraph 2.

<sup>76</sup> See document WIPO/GRTKF/IC/4/15 (« Report »), paragraph 125(iii).

concerning TK and genetic resources are dealt with in document WIPO/GRTKF/IC/5/10. There remain, however, several possibilities for building upon this experience with developing defensive protection measures. At the same time, the work of the Committee has seen a strong concern that defensive protection should not be pursued as an end in itself, and that positive protection measures be developed and applied so that TK holders and communities may derive benefits from the positive exercise of rights related to TK, and not merely prevent. Accordingly, any work on defensive protection methods will need to proceed in conjunction with continuing consideration of approaches to positive protection of TK (see document WIPO/GRTKF/IC/5/8), and also with capacity-building programmes to ensure that no decisions are made to document, record, disclose or make public TK-related information unless the community or individuals making the disclosure are aware of the full implications of this step (see document WIPO/GRTKF/IC/5/5).

*Recommendations on uses for defensive protection*

80. One possible means of improving defensive protection of TK and genetic resources within the patents system would be to clarify the legal criteria that apply to prior art. National and regional approaches vary as to what standards prior art must meet in order to count as relevant in the determination of patent validity. Differences may apply depending on where the prior art was made available to the public, the circumstances or extent of disclosure of the prior art, and whether it was orally disclosed or disclosed in written form. Some commentators have proposed that a broad definition of prior art be developed and applied.<sup>77</sup> At the international level, this might entail harmonization of substantive patent law in this regard, a matter which is already under discussion by the WIPO Standing Committee on Patent Law (SCP).

81. At the practical level, planning and implementation of defensive protection strategies would be assisted by the compilation of information about the criteria that apply to the determination of relevant prior art in various jurisdictions, so that where defensive publication is made for a particular purpose, it would achieve the intended objectives. This information could be compiled on the basis of a questionnaire concerning key aspects of prior art (such as the nature of disclosure, including enablement, the nature of public access required, criteria concerning the medium, location, written or oral character, and documentation of the date of disclosure); such a compilation would be a practical tool for defensive protection activities.

82. Another possibility would be to prepare recommendations or guidelines for national patent offices concerning searches in the area of inventions linked to TK (within specific technical fields) or genetic resources. This could put into a practical context the developments outlined above concerning the IPC and PCT minimum documentation. Recommendations could call for search and examination to take into account disclosed genetic resources and TK as prior art, as well as the possibility of conducting international type searches for national applications, subject to the capacities of concerned IP offices, in particular those of developing and least developed countries.

<sup>77</sup> See, for example, 'Integrating Intellectual Property Rights and Development Policy,' Commission on Intellectual Property Rights, London, 2002, page 83.

83. Rule 34 of the PCT Regulations sets a minimum standard for documentation which shall be consulted in the context of International Searches on international applications. Yet the documentation consulted during these searches on national applications varies widely according to the law and practice of national and regional patent-granting authorities. It has been suggested in a more general context that examination procedures should integrate more effectively the guidelines for “international-type searches” into the examination process for national patent applications.<sup>78</sup> The PCT further provides that, if the national law of the Contracting State so permits, an “international-type search” may be carried out on national applications at the request of the applicant. Article 15(5)(a) of the PCT provides that “the applicant who files a national application with the national Office of Contracting State may, subject to the conditions provided for in such law, request that a search similar to an international search (“international-type search”) be carried out on such application.”<sup>79</sup>

84. Besides the applicant, the national Office of a Contracting State “may subject any national application filed with it to an international-type search”<sup>80</sup>; if the national law so permits. The international-type search is carried out by the International Searching Authority which would become competent for an international search if the national application were an international application.<sup>81</sup> In some jurisdictions, examiners must already perform an “international-type” search as part of every examination of a national application.<sup>82</sup> In practice, however, examiners mostly perform international-type searches only for applications that enter the national stage after they have gone through the international stage under the PCT.<sup>83</sup>

#### *Recommendations on uses for positive protection*

85. Information recorded under the patents system has the dual function of defining positive patent rights (especially the claims) but also disclosing technical information which forms part of the prior art against which later claims are assessed. A similar dual function may apply in those cases where registries have been set up under national law as part of *sui generis* protection systems for TK and related components of biological diversity.<sup>84</sup> Moreover, practical and operational experience with registration of this information may be equally relevant to positive protection and defensive protection mechanisms.<sup>85</sup> Experiences gained by IP offices with the use of TK and genetic resource databases for defensive protection could provide lessons for the use of such mechanisms for both defensive and positive protection. Some of the legal and operational questions that may be addressed include:

<sup>78</sup> See, for example, comments presented in response to USPTO Request for Comment on Issues Related to the Identification of Prior Art During the Examination of Patent Application (RIN 0651-ZA02, Federal Register Notice: May 27, 1999 (64 Fed. Reg. 28803)).

<sup>79</sup> Article 15(5)(a), PCT.

<sup>80</sup> Article 15(5)(b), PCT.

<sup>81</sup> Article 15(5)(c), PCT.

<sup>82</sup> For example, in the United States of America, see 37 CFR § 1.104(a)(3).

<sup>83</sup> In the United States, however, 37 C.F.R. § 1.9 defines a “national application” to include any U.S. application for patent filed under 35 U.S.C. § 111, not only applications entering the national stage from international applications.

<sup>84</sup> This is the case, for example, for the IP-granting authorities of Panama and Peru, who are responsible for implementing their national *sui generis* regimes respectively.

<sup>85</sup> See document WIPO/GRTKF/IC/4/14, Annex, page 3.

- (a) How to integrate local languages into registries?
- (b) How to integrate knowledge from oral traditions if it is registered?
- (c) Registration of sacred knowledge;
- (d) Registration of secret knowledge;
- (e) Issues of double registration;
- (f) Issues of distorted registration;
- (g) Access conditions to knowledge:
  - (i) Structures of tiered access levels for registries (e.g. international public level access; national public level access; community level access; confidential information);
  - (ii) Metadata solutions for administering access conditions to knowledge (e.g. agreed metadata to specify the different types of registrations);
  - (iii) Technical security measures and technological protection measures for tiered access levels;
- (i) Minimum data fields for registers: what is the minimum information on rights granted, rightholders and claimed subject matter, which is needed for effective recognition, management and enforcement of rights (both in the jurisdiction in which the registry is established and in other jurisdictions)?;
- (j) Who is entitled to register? (only nationals, also foreigners; only communities?);
- (k) The type of subject matter to be registered (only biodiversity-related TK or all kinds of TK);
- (l) Management and ownership of registries;
- (m) Recognition of requirements under customary laws if the registry concerns TK;
- (n) How can registrations be classified for efficient and language-independent search and retrieval?;
- (o) Publication of registrations: How to put the public on notice (Internet publication, official gazettes, publicly accessible lists, etc);
- (p) Interoperability of registers:
  - (i) Language-independent interoperability;
  - (ii) Development of agreed identifiers and data fields;
  - (iii) Development of agreed basic procedures for registries and registrations.

86. If there were to be a bilateral or international recognition of registries and registrations in the future, an extensive exchange of rights information would indeed take place.

Local registers would therefore have to be able to effectively and efficiently exchange rights information. Such an exchange would require a minimum of interoperability or agreed standards among the various registries. It might therefore be useful to develop recommended elements and modalities for such registration mechanisms, based on the above-mentioned work of the Committee, in order to ensure the future interoperability of such registration mechanisms for both defensive and positive protection purposes. This work may be coordinated with the development of an annotated menu of policy options for positive protection of TK, as proposed in document WIPO/GRTKF/IC/5/8.

## VIII. CONCLUSION

87. The Activities adopted by the Committee under Task B.3 have all either been delivered or are currently in the final stages of completion. Many of them have been passed on to other relevant WIPO bodies for further implementation, such as the PCT/MIA and the PCT/CTC. The Committee's initial work program on defensive protection can be seen as successfully carried out. There remain, however, a few areas where future work could be undertaken to improve the defensive and positive protection of TK and genetic resources. In particular, there is scope for broader application of the practical lessons learned from ensuring defensive protection of TK and genetic resources.

88. Any work on defensive approaches should, however, be undertaken within the context of a comprehensive approach to the protection of TK, which takes account of the needs, widely expressed, for more effective positive protection and for any holders or custodians of TK to be fully informed of the consequences of making any disclosure of their TK, especially when disclosure leads to publication of the TK or its more ready access by members of the public.

*89. The Committee is invited: (i) to call for further responses to be submitted on the Questionnaire on Databases and Registries Related to TK and Genetic Resources (WIPO/GRTKF/IC/Q.4); (ii) to consider, amend and adopt the technical proposals contained in document WIPO/GRTKF/IC/4/14, for forwarding to the Standards and Documentation Working Group of the SCIT for inclusion in the WIPO Industrial Property Documentation Handbook and other appropriate uses; and (iii) to consider future work including a questionnaire on prior art criteria and development of draft recommendations to IP-granting authorities concerning registration mechanisms for defensive and positive protection.*

[Annex I follows]





## ANNEXI

Table of Deliverables Produced by  
the Intergovernmental Committee on  
Defensive Protection of TK and Genetic Resources

Activity Adopted by the Committee As Set Out in Document WIPO/GRTKF/IC/2/6:	Deliverables Produced by the Intergovernmental Committee :	Outcomes in other WIPO and UN Bodies, based on the Committee's work:	Relevant Documents
<p><i>Activity 1</i> : To compile an inventory of existing TK -related periodicals, which document and disclose TK, with a view to discussing a possible recommendation that certain periodicals may be considered by the International Search Authorities for integration into the minimum documentation list under the PCT.</p>	<ul style="list-style-type: none"> <li>- WIPO Inventory of TK -related Periodicals;</li> <li>- WIPO Inventory of TK -related Databases;</li> </ul>	<ul style="list-style-type: none"> <li>- PCT Committee on Technical Cooperation Considered the Inventories;</li> <li>- PCT Assembly Considered the Inventories;</li> <li>- PCT Meeting of International Authorities Decided to Integrate TK Periodicals into PCT Minimum Documentation;</li> <li>- Certain Periodicals are currently being selected by PCT/CTC for Integration into PCT Minimum Documentation ;</li> </ul>	<ul style="list-style-type: none"> <li>- WIPO/GRTKF/IC/2/6</li> <li>- WIPO/GRTKF/IC/3/5</li> <li>- WIPO/GRTKF/IC/3/6</li> <li>- PCT/CTC/20/4</li> <li>- PCT/CTC/20/5</li> <li>- PCT/A/3/10</li> <li>- PCT/MIA/7/3</li> <li>- PCT/MIA/7/5</li> </ul>

<p><i>Activity 4</i> :To study the feasibility of electronic exchange of public domain TK documentation data, including through the establishment of international online TK databases and digital libraries .</p>	<ul style="list-style-type: none"> <li>- WIPO Portal of Online Databases of Disclosed TK and Genetic Resources ;</li> <li>- Health Heritage Test Database of Ayurvedic Traditional Medicine (at the request of the Government of India).</li> </ul>	<ul style="list-style-type: none"> <li>- PCT Meeting of International Authorities Identified Option to Establish a PCT /ISA Portal of Online Databases for International Searches Related to TK and Genetic Resources ;</li> <li>- CBD Clearing -house Mechanism incorporates WIPO Portal;</li> </ul>	<ul style="list-style-type: none"> <li>- WIPO/GRTKF/IC/2/6</li> <li>- WIPO/GRTKF/IC/3/6</li> <li>- WIPO/GRTKF/IC/4/14</li> <li>- PCT/MIA/7/5</li> </ul>
<p><i>Activity 5</i>: To examine the applicability of existing IP documentation standards to TK-related subject matter and the relationship of these standards with existing TK documentation standards.</p>	<p>Technical Proposal on Databases and Registries of TK and Genetic/Biological Resources, including:</p> <ul style="list-style-type: none"> <li>- Agreed Standard for Data Fields and Identifiers for Databases and Registries</li> <li>- Analysis of the Application of WIPO Documentation Standards: ST.9, ST.81, etc.</li> </ul>		<ul style="list-style-type: none"> <li>- WIPO/GRTKF/IC/2/6</li> <li>- WIPO/GRTKF/IC/3/6</li> <li>- WIPO/IPTK/COK/02/1 Prov.</li> <li>- WIPO/GRTKF/IC/4/14</li> </ul>
<p><i>Activity 6</i> : To discuss ways and means of providing assistance to TK documentation initiatives to manage the IP implications during the documentation process.</p>	<ul style="list-style-type: none"> <li>- WIPO Toolkit for IP Management When Documenting TK and Genetic Resources.</li> </ul>	<p>The draft Toolkit was considered by the following UN meetings:</p> <ul style="list-style-type: none"> <li>- UNEP/UNU Scoping Meeting on Capacity Building Approaches for Access to Genetic Resources and Benefit-sharing;</li> <li>- CBD Open -ended Expert Workshop on Capacity -building for Access to Genetic Resources and Benefit -sharing;</li> <li>- CBD Ad Hoc Technical Expert Group on Traditional</li> </ul>	<ul style="list-style-type: none"> <li>- WIPO/GRTKF/IC/2/6</li> <li>- WIPO/GRTKF/IC/3/5</li> <li>- WIPO/GRTKF/IC/4/5</li> <li>- WIPO/GRTKF/IC/5/5</li> </ul>

		Knowledge and Clearing - House Mechanism of the Convention on Biological Diversity .	
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[Annex II follows]

## ANNEXII

## SYSTEM-WIDE INFORMATION NETWORK FOR GENETIC RESOURCES (SINGER)

The *System-wide Information Network for Genetic Resources* (SINGER), exists to ensure that information about the diversity of plants that contribute to food and agriculture is available to all. Much of the diversity is stored in gene banks around the world, with the largest collections of crops important for the poorest people held by the Future Harvest Centres, a network of 16 food and environmental research centres supported by the Consultative Group on International Agricultural Research (CGIAR).

The Future Harvest Centres hold more than half a million samples of crop, forage and agroforestry plants in trust for the world community under agreements signed with the United Nations Food and Agriculture Organization (FAO) in 1994. The agreements require Centres to make all information on the in-trust collection easily available without restriction, just as the material itself is available. SINGER was established under the auspices of the CGIAR System-wide Genetic Resources Programme (SGRP) to help Centres meet these responsibilities.

The collections and information about them are held by the gene banks in eleven Centres across the world. SINGER brings together these independent gene bank databases and permits their easy access and interrogation.

On the World Wide Web (<http://singer.cgiar.org>) and CD-ROMs since 1997, SINGER today permits 'one stop' public access to information on more than half a million in-trust samples of crop, forage and agroforestry plants.

SINGER provides access to information on collections of these crop, forage and agroforestry plants held by Future Harvest Centres. A list of plants and Centres is provided in Figure 1.

<i>Figure 1:</i> <i>Genetic Resources</i>	<i>CENTRE</i>
Agroforestry trees	ICRAF
Andean roots and tubers	CIP
Bambara groundnut	IITA
Banana and plantain	IPGRI
Barley	ICARDA
Bean	CIAT
Cassava	CIAT, IITA
Chickpea	ICRISAT, ICARDA
Cowpea	IITA
Fababean	ICARDA
Forages	CIAT, ICARDA, ILRI
Groundnut	ICRISAT
Lentil	ICARDA
Maize	CIMMYT
Minor millets	ICRISAT
Pearl millet	ICRISAT

Pigeonpea	ICRISAT
Potato	CIP
Rice	IRRI, WARDA
Sorghum	ICRISAT
Soybean	IITA
Sweetpotato	CIP
Wheat	CIMMYT, ICARDA
Yam	IITA

SINGER offers specialized and innovative data searching and retrieval features that integrate multiple querying with mapping (global, regional, country), statistical (mean, variance and standard deviation) and graphical (scatter and distribution plots) functions. SINGER also offers users the opportunity to download data for further analysis. SINGER registers an average of 10,000 searches a month from researchers, plant breeders, farmers and conservers. This represents an increase of 300% over the past 4 years, a clear demonstration that the users of SINGER value its ability to help them in their work.

The information in SINGER is crucial to its community of users. For example, knowledge of the original source of the material and where it was collected can help users to make more effective use of diversity. Knowing where samples were collected has made it possible to restore local varieties to regions devastated by war or natural disasters.

SINGER makes available information on the characteristics and performance of each individual sample held in the Future Harvest gene banks. Researchers have amassed this knowledge over decades and it can now be used to pinpoint the sample that might serve a researcher's goals best.

For example, researchers looking for chickpea accessions with high protein content can use SINGER to identify samples with this characteristic in the collections at ICRISAT and ICARDA (International Crops Research Institute for the Semi-Arid Tropics and International Center for Agricultural Research in the Dry Areas, respectively).

SINGER contains some 30 years worth of records on the supply of samples in response to requests from individuals and from the research and plant improvement programmes of Centres and national institutions. These have been used to map the size and direction of flows of in-trust material. The analysis shows that all countries are net beneficiaries of the system. Countries of the FAO Commission on Genetic Resources for Food and Agriculture recognized SINGER as a model information network that could contribute to a multilateral system for exchange of plant genetic resources.

SINGER is now driving force in information networking inside and outside the CGIAR, meeting the needs of researchers, plant breeders, farmers and conservers in their efforts to sustain food security and improve production. It has transformed itself from being simply a source of information into a dynamic network that harnesses expertise and information about genetic resources to further the global exchange of information for genetic resources conservation and use.

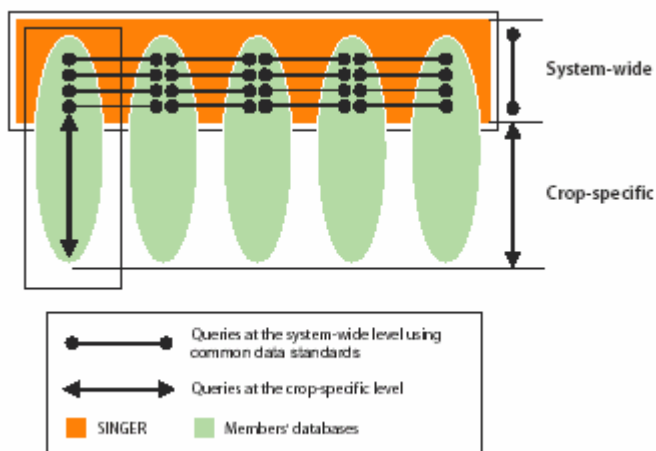
At the core of SINGER are the specialists at the individual Centres who document the genetic resources and manage the information systems. Collaboration among these specialists

to make available not only high-quality information but also their expertise on the plant collections underpins SINGER.

Standards are vitally important to ensure compatibility among different sources of information and thus to facilitate the management and exchange of knowledge. SINGER is using its leading position to promote common standards worldwide to ensure that bridges can be built between myriad sources of genetic resources information now and in the future.

The use of common data standards for key descriptors such as taxonomy and country names allows system-wide access and searches across multiple databases while retaining the autonomous structure and management of the individual databases (see Figure 2).

Figure 2



SINGER stays at the forefront of developments in computer software, hardware and information and communication technologies. Cost-effectiveness as much as compatibility and flexibility guide the choice of technologies employed in SINGER and by its partners. SINGER has adopted open source software and offers free access to the applications it develops. These cost-cutting solutions are being promoted within and outside the network, making it easier for all in the genetic resources community to access the most up-to-date technologies.

By building and linking networks at both regional and crop levels, SINGER aims to contribute to the FAO World Information and Early Warning System (WIEWS) on Plant Genetic Resources for Food and Agriculture and thereby assist in the development of a global information system for plant genetic resources conservation and use.

Quite apart from its direct involvement in innumerable breeding programmes, SINGER finds many other uses: assisting the restoration of local genetic resources in times of crisis; tracking material flows to examine possible violations of the in-trust agreements; pre-screening accessions for particular traits; indicating under-represented areas for future collecting missions; identifying accessions for repatriation; and supporting basic research, for example on taxonomic relationships among accessions.

SINGER underpins the efforts of the Future Harvest Centres and other stakeholders to alleviate poverty by making it easier and more efficient to obtain and make use of genetic resources and related information.

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[End of Annex II and of document]